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EXAMINER	
QAZI, SABIHA NAIM	
ART UNIT	**PAPER NUMBER**
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/577,489	WOOD ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/19.2006*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-40,42-45 and 47-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-40,42-45 and 47-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Final Office Action

Claims 28-40, 42-45 and 47-59 are pending. No claim is allowed at this time.

Summary of this Office Action dated Friday, Sept. 29, 2006

1. Information Disclosure Statement
2. Copending Applications
3. Specification
4. 35 USC § 112 --- First Paragraph Written Description Rejection
5. 35 USC § 103(a) 1st Rejection
6. 35 USC § 103(a) 2nd Rejection
7. Response to Remarks
8. CONCLUSION
9. Communication

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Copending Applications

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See Dayco Products Inc. v. Total Containment Inc., 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112—Written Description Rejection

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-40, 42-45, and 47-59 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Following reasons apply.

Applicant had no possession at the time this application was filed of claimed "Method of delivering" and the steps as claimed (claims 28-40, 42-45 and 47-59) and method of treating respiratory illness such as AIDS, AIDS-related pneumonia, respiratory distress syndrome and various others listed in claim 44.

The particle size required in claim 28 is huge (50 microns is very large and is ***NOT respirable***) and includes essentially all of the pharmaceutical aerosol art (considering only active particle sizes not the size of carrier particles, like lactose). There is no limitation of the composition's form, so the composition could read on solutions, suspensions, and "dry powders" (assuming the water present is a small percentage of the composition and is just water of hydration associated with the active and/or the carrier).

On another note, claim 44 is drawn to a method of treatment and also because AIDS is sometimes treated by the administration of several drugs, some of which may be proteins. The priority goes back to the 90's and at the time of invention whether Applicant was really in possession for the delivery of proteinic proteins via an aerosol (something that's not easy to do), assuming these were typical drugs used in AIDS treatments at the time of Applicant's invention.

Claim 37 is drawn to selected therapeutic agents consist of analgesics, anti-inflammatory agents, anthelminteics, antibiotics, anticoagulants, anti-diabetic agents, thyroids agents and includes a long list of agents. Specification in example 1 discloses beclamethasone. Applicants at the time of invention did not possess all the invention as presently claimed. The therapeutic agents are different class of compounds having different chemical structures and different chemical properties. All the therapeutic agents as in claim 28 and 37 cannot have the same mode of action, effective doses,

properties and activities. Each requires a complete study of effective dosages, specific delivery, and treatment. In addition a large number of surface modifiers as in claim 28 and specifically named in claim 32 requires a undue experimentation to find out specific ratios. The specific ratios are in claims 34 to 36 and claims 47 to59. Furthermore, there is no description for use of "at least two surface modifiers" as in claim 33.

Claim 45 requires "the aerosol further comprises a liquid propellant", clarifies that applicants are not using "only water" in their invention.

Example 1 in the disclosure does not explain the description requirements for the reasons cited above.

Applicant is kindly requested to show that at the time of invention Applicants were in possession of the claimed invention such as "method of delivering" and steps as claimed and further claim 44 is drawn to method of use for a large number of diseases.

Specification on page 18 contains Example 1 using beclomethasone (BDP) as therapeutic agent. The example does not contain the same steps of method of delivery as claimed. Applicant is requested to explain. Example 2 on page 24 uses a contrast agent.

The written description requirement prevents applications from using the amendment process to update the disclosure in their disclosures (claims or

specification) during the pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of the invention. See 35 USC 132. The function of description requirement is to ensure that the inventor had possession, as of filing date of the application relied on, the specific subject matter claimed by him.

See *Genetech*, 108 F 3d 1361, 1365 (Fed. Cir. at 1366, 78, 1999).

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had the possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language. See In re Kaslow, 707 F 2d 1366, 1375 (Fed. Cir. 1983).

In the present case Applicant has no possession of method of delivering (claim 28) and method of treating respiratory illness such as asthma, AIDS, AIDS related pneumonia (claim 44) as now claimed in this application.

See MPEP 2163.06, for Applicant convenience relevant portion is as follows:

GENERAL PRINCIPLES GOVERNING COMPLIANCE WITH THE "WRITTEN DESCRIPTION" REQUIREMENT FOR APPLICATIONS

The first paragraph of 35 U.S.C. **112** requires that the "specification shall contain a written description of the invention * * *." This requirement is separate and distinct from the enablement requirement. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991). >See also *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920-23, 69 USPQ2d 1886, 1890-93 (Fed. Cir. 2004) (discussing history and purpose of the written description requirement); *In re Curtis*, 354 F.3d 1347, 1357, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004) ("conclusive evidence of a claim's enablement is not equally conclusive of that claim's satisfactory written description").< The written description requirement has several policy objectives. "[T]he 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed." *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what the applicant claims as the invention. See *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). The written description requirement of the Patent Act promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their

patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., >*Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003);< *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. However, a showing of possession alone does not cure the lack of a written description. *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, **>323 F.3d 956, 969-70,< 63 USPQ2d 1609, 1617 (Fed. Cir. 2002). Much of the written description case law addresses whether the specification as originally filed supports claims not originally in the application. The issue raised in the cases is most often phrased as whether the original application provides "adequate support" for the claims at issue or whether the material added to the specification incorporates "new matter" in violation of 35 U.S.C. **132**. The "written description" question similarly arises in the interference context, where the issue is whether the specification of one party to the interference can support the newly added claims corresponding to the count at issue, i.e., whether that party can "make the claim" corresponding to the interference count. See, e.g., *Martin v. Mayer*, 823 F.2d 500, 503, 3 USPQ2d 1333, 1335 (Fed. Cir. 1987). In addition, early opinions suggest the Patent and

Trademark Office was unwilling to find written descriptive support when the only description was found in the claims; however, this viewpoint was rejected. See *In re Koller*, 613 F.2d 819, 204 USPQ 702 (CCPA 1980) (original claims constitute their own description); accord *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); *accord In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). It is now well accepted that a satisfactory description may be in the claims or any other portion of the originally filed specification. These early opinions did not address the quality or specificity of particularity that was required in the description, i.e., how much description is enough.

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.,* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d

at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it"). "Compliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" *Enzo Biochem*, **>323 F.3d at 963<, 63 USPQ2d at 1613. An application specification may show actual reduction to practice by describing testing of the claimed invention or, in the case of biological materials, by specifically describing a deposit made in accordance with 37 CFR **1.801** *et seq.* See *Enzo Biochem*, **>323 F.3d at 965<, 63 USPQ2d at 1614 ("reference in the specification to a deposit may also satisfy the written description requirement with respect to a claimed material"); see also Deposit of Biological Materials for Patent Purposes, Final Rule, 54 FR 34,864 (August 22, 1989) ("The requirement for a specific identification is consistent with the description requirement of the first paragraph of 35 U.S.C. **112**, and to provide an antecedent basis for the biological material which either has been or will be deposited before the patent is granted." Id. at 34,876. "The description must be sufficient to permit verification that the deposited biological material is in fact that disclosed. Once the patent issues, the description must be sufficient to aid in the resolution of questions of infringement." Id. at 34,880.). Such a deposit is not a substitute for a written description of the claimed invention. The written

description of the deposited material needs to be as complete as possible because the examination for patentability proceeds solely on the basis of the written description. See, e.g., *In re Lundak*, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985). See also 54 FR at 34,880 ("As a general rule, the more information that is provided about a particular deposited biological material, the better the examiner will be able to compare the identity and characteristics of the deposited biological material with the prior art.").

A question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently (see, e.g., *Enzo Biochem*, **>323 F.3d at 968<, 63 USPQ2d at 1616 (Fed. Cir. 2002); *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398), a new or amended claim wherein a claim limitation has been added or removed, or a claim to entitlement of an earlier priority date or effective filing date under 35 U.S.C. **119**, **120**, or **365(c)**. Most typically, the issue will arise in the context of determining whether new or amended claims are supported by the description of the invention in the application as filed (see, e.g., *In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989)), whether a claimed invention is entitled to the benefit of an earlier priority date or effective filing date under **35 U.S.C. 119**, **120**, or **365(c)** (see, e.g., *New Railhead Mfg. L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 63 USPQ2d 1843 (Fed. Cir. 2002); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998); Fiers v. Revel, 984 F.2d 1164, 25

USPQ2d 1601 (Fed. Cir. 1993); *In re Ziegler*, 992 F.2d 1197, 1200, 26 USPQ2d 1600, 1603 (Fed. Cir. 1993)), or whether a specification provides support for a claim corresponding to a count in an interference (see, e.g., *Fields v. Conover*, 443 F.2d 1386, 170 USPQ 276 (CCPA 1971)). Compliance with the written description requirement is a question of fact which must be resolved on a case-by-case basis. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991).

2163.06 Relationship of Written Description Requirement to New Matter

Lack of written description is an issue that generally arises with respect to the subject matter of a claim. If an applicant amends or attempts to amend the abstract, specification or drawings of an application, an issue of new matter will arise if the content of the amendment is not described in the application as filed. Stated another way, information contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter.

There are two statutory provisions that prohibit the introduction of new matter: **35 U.S.C. 132** - No amendment shall introduce new matter into the disclosure of the invention.

35 U.S.C. 112 Specification. - Patent Laws

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Rejection under 35 USC § 103(a) 1st Rejection

Claims 28-40, 42-45, and 47-59 are rejected under 35 USC § 103(a) as being unpatentable over LIVERSIDGE et al (US Patent No. 5,145,684) and FOLKE MOREN Aerosols in Medicine, Principles, Diagnosis and Therapy, (1993) Elsevier Science Publisher, Chapter 13, pages 321-350. Both references teach a method and use of drug by inhalation aerosols for drug delivery into airways that embraces Applicant's claimed invention. See the entire document.

LIVERSIDGE et al. teaches that commercial air jet milling techniques provide particles ranging in average particle size from as low as 1,000 to 50,000 nm (1 to 50 microns). The reference also teaches crystalline drug particle having a surface modifier adsorbed on the surface thereof in an amount sufficient to maintain an effective particle size of less than 400 nm. See the entire document, especially lines 47-50 in col. 1, claims, and examples.

Instant claims differ from LIVERSIDGE et al in that the reference does not teach the use of aerosols.

MOREN teaches the use of inhalation aerosols for drug delivery into airways, mainly to provide a local effect in the upper or lower respiratory tract. It also teaches that drugs are widely used for local effect in the lower respiratory tract. Bronchodilators, corticosteroids, anticholinergics and antiallergic drugs are administered by means of oral inhalation. The advantages being decreased systemic side effects, and in some cases rapid onset of action See 2nd paragraph on page 321. See also 1st and 2nd paragraphs on page 322, see nasal inhalation on page 337, particle size on page 338, see section 4.1 and 4.1.1 where aqueous aerosols are taught.

It would have been obvious to one skilled in the art at the time of invention was made to prepare the method of delivering an aerosol to lungs as claimed by the combined teachings of the two references cited above for the treatment of respiratory diseases by using aerosols because LIVERSIDGE et al teaches the average particle size, surface modifier, and all other limitations of the presently claimed invention and

MOREN teaches aerosols and delivery to respiratory tract using poorly soluble drugs such as steroids. The Markush groups of surfactants are noted.

In present claims there is no limitation of the composition's form, so the composition could read on solutions, suspensions, and "dry powders" (assuming the water present is a small percentage of the composition and is just water of hydration associated with the active and/or the carrier).

The particle size required in claim 28 contains huge sizes (50 microns is very large and is ***NOT respirable***) and includes essentially all of the pharmaceutical aerosol art (considering only active particle sizes not the size of carrier particles, like lactose). There is no limitation of the composition's form, so the composition could read on solutions, suspensions, and "dry powders" (assuming the water present is a small percentage of the composition and is just water of hydration associated with the active and/or the carrier).

On another note, claim 44 is drawn to a method of treating respiratory illness such as AIDS, AIDS-related pneumonia, respiratory distress syndrome and various others listed in claim 44. AIDS is sometimes treated by the administration of several drugs, some of which may be proteins.

Examiner notes that claim 45 requires "the aerosol further comprises a liquid propellant" clarifies that applicants are not using "only water" in their invention.

Referring to claim 44 Applicants have not shown how the method of treating various diseases is different from the prior art teaching by using their delivery method.

In absence of any criticality and/or unexpected results instant invention is considered *prima facie* obvious to one skilled in the art.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Rejection under 35 USC § 103(a) 2nd Rejection

Claims 28-40, 42-45, and 47-59 are rejected under 35 USC § 103(a) as being unpatentable over LIVERSIDGE et al (US Patent No. 5,145,684), A.R. GENNARO Remington's Pharmaceutical Sciences, 17th Edition, (1985), Chapter 93, pages 1670-1677 and DIETER KOHLER, Aerosols in Medicine, Principles, Diagnosis and Therapy, Edited by F. Moran, Chapter 12, (1993), pages 303 319. All the references teach a method that embraces Applicant's claimed invention.

LIVERSIDGE et al. teaches that commercial air jet milling techniques provide particles ranging in average particle size from as low as 1,000 to 50,000 nm (1 to 50

microns). The reference also teaches crystalline drug particle having a surface modifier adsorbed on the surface thereof in an amount sufficient to maintain an effective particle size of less than 400 nm. See the entire document, especially lines 47-50 in col. 1, claims, and examples.

Instant claims differ from LIVERSIDGE et al in that LIVERSIDGE does not teach aerosols.

GENNARO and KOHLER reference teache the use of aerosol for poorly soluble drugs, absorbance, particle size and various others related to aerosols.

GENNARO reference teaches pharmaceutical aerosols in the form of solutions, suspensions, emulsions, powders and semisolids, see the entire document (see especially Table V in the left column of page 1672). The reference also teaches the preparation of aerosols for antibiotics, steroids and other difficultly soluble compounds (see last two paragraphs on page 1672 in the right column. See particle size and drug delivery into respiratory airways on pages 1674 and 1675, Table IX on page 1676 where steroids and other poorly soluble drugs are listed as medicinal agents having high potential for use as aerosol inhalation products.

KOHLER teaches the advantages of drug administration via aerosols for systemic treatment over oral routes of the compounds that are poorly soluble. See the entire document especially 2nd para on page 305, TABLE 1, section 3.1 on page 309-311, TABLE 2 and section 3.3 on page 313 and last paragraph on page 315.

It would have been obvious to one skilled in the art at the time of invention was made to prepare the method of delivering an aerosol to lungs as claimed for the

treatment of respiratory diseases by the combined teachings of the above cited references, because LIVERSIDGE et al teaches the average particle size, surface modifier, and all other limitations of the presently claimed invention and GENNARO and KOHLER references teach the use of aerosols for poorly soluble drugs and inhalation products and treatment of asthma and other respiratory illness.

At the time of invention the use of aerosols was known in the art. All the claimed invention is taught by LIVERSIDGE except aerosols. It would have been prima facie *obvious to use aerosols because prior art teaches the use for the same purpose.*

Referring to claim 44 Applicants have not shown how the method of treating various diseases is different from the prior art teaching. How the method of treating is better from the prior art teachings.

There is no limitation of the composition's form, so the composition could read on solutions, suspensions, and "dry powders" (assuming the water present is a small percentage of the composition and is just water of hydration associated with the active and/or the carrier).

In absence of any criticality and/or unexpected results instant invention is considered *prima facie* obvious to one skilled in the art.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Response to Remarks

- The 35 USC § 103(a) rejections over US 5747001 (WIEDMANN et al), US 6264922 (WOOD et al.), and US 5145684 (LIVERSIDGE et al.) is withdrawn as a terminal disclaimer has been filed and approved.
- Arguments were fully considered but are not found persuasive therefore rejections are maintained for the same reasons as set forth in our previous office action.
- Examiner could not find the support on page 2, line 35, through page 3, line 5 for claims 28-40, 42-45 and 47-59 for the steps in claim 28 and subject matter of other dependent claims. The test for determining compliance with the written description requirement is whether the disclosure of the application as **originally filed reasonably conveys** to one skilled in the art that the inventor had the possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language. See In re Kaslow, 707 F 2d 1366, 1375 (Fed. Cir. 1983).

- Written description has not been addressed completely. Applicant is requested to explain where is the support of these method steps in claim 28 and method of use as in claim 44. The example in specification does not contain the claimed steps. Further possession of all the pending claims including claim 44 needs explanation.
- Applicant's response is silent over claim 44. How the method of administering is applied to treat diseases differently from the prior art. The arguments filed on 2/04/04 Applicant argue that "it was not known that nanoparticulate formulations could be incorporated into aerosol formulations, much less any that could be delivered to a mammal's lung as discovered and claimed by present invention". Examiner had replied in detail in our previous office actions for these arguments, and obviousness rejections, which has been repeated again by the Applicants.
- Since there are issues about written description requirement, the Examiner requests the Applicants to explain in view of written description that claimed invention was possessed by Applicants in 08/394,103 and as well as in the specification of present application for the presently claimed invention (claims 28-40, 42-45, and 47-59). The comparison as listed in the remarks in pages 8-9 is not persuasive as claimed for the reasons cited above in written description because whether or not inventor had the possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed

language. For example Applicants had no possession of the steps and method of treating respiratory illness at the time this application was filed.

- Examiner respectfully disagree with arguments about MOREN reference. MOREN teaches the use of inhalation aerosols for drug delivery into airways, mainly to provide a local effect in the upper or lower respiratory tract. It also teaches that drugs are widely used for local effect in the lower respiratory tract. Bronchodilators, corticosteroids, anticholinergics and antiallergic drugs are administered by means of oral inhalation. The advantages being decreased systemic side effects, and in some cases rapid onset of action See 2nd paragraph on page 321. See also 1st and 2nd paragraphs on page 322, see nasal inhalation on page 337, particle size on page 338, see section 4.1 and 4.1.1 where aqueous aerosols are taught. There is a reasonable expectation of success for one skilled in the art who would like to prepare the aerosols of poorly soluble drugs by combining the teachings of LIVERSIDGE and MOREN.
- Applicant argues that that on page 310, KOHLER teaches that the drug must be in solution to be suitable for nebulization as an aqueous aerosol. It is unclear where will be the applicants claimed drug when prepared for aerosol formulation. Instant claim 45 requires "the aerosol further comprises a liquid propellant", clarifies that applicants are not using "only water" in their invention.

- Similarly GENNARO discloses suspensions and propellants/solvent system.
- Claim 37 is drawn to selected therapeutic agents consist of analgesics, anti-inflammatory agents, anthelminteics, antibiotics, anticoagulants, anti-diabetic agents, thyroids agents and includes a long list of agents. Specification in example 1 discloses beclamethasone. Applicants at the time of invention did not possess all the invention as presently claimed. The therapeutic agents are different class of compounds having different chemical structures and different chemical properties. Therefore, all the therapeutic agents as in claim 28 and 37 cannot have the same mode of action, doses, properties and activities. Each requires a complete study of effective dosages, specific delivery, and treatment. In addition a large number of surface modifiers as in claim 28 and specifically named in claim 32 requires an undue experimentation to find out specific ratios. The specific ratios are in claims 34 to 36 and claims 47-59. Furthermore, there is no description for use of "at least two surface modifiers" as in claim 33. One skilled in the art would not be able to practice the invention at the time of invention was made.

- Applicant is kindly requested to explain what are the key differences, which is not taught by the references. Applicant is also kindly requested to response to written description requirement. As has been said earlier

that the test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had the possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language. Instant invention as claimed is considered obvious over the prior art of record for the reasons cited above.

- This Application is a CIP of 08/394103 filed on Feb. 24, 1995, now abandoned. The subject matter in this application is different from the subject matter in 08/394103.

- In order to advance the prosecution Applicant may consider calling the Examiner to discuss the issues surrounding this application.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi, Ph.D. whose telephone number is 571-272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, Ph.D. can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Qazi

SABIHA QAZI, PH.D
PRIMARY EXAMINER